

Proposed Alternate Restriction of Claims

Applicants propose an alternate grouping of the claims as follows:

Group 1: claims 1 - 18 antibodies and methods of making antibodies to certain CYP1B1 epitopes.

Group 2: claim 19 methods of medical treatment.

Group 3: claim 20 a peptide consisting essentially of certain specific sequences.

Group 4: claims 21-25 assay methods comprising detecting antibodies of Group 1.

REMARKS

Applicants propose that the Office agree to prosecute the present application based on the proposed alternate grouping. Should such a condensed grouping be accepted, Applicants would elect proposed alternate Group 1. The proposed grouping would be proper according to the rules regarding unity of invention and would not impose a serious burden on the Office.

An inventive linkage exists between the alternate sequences of the claims. The sequences are continuations of each other in a region of the CYP1B1 protein sequence identified as substantially unique and available for antibody interactions. In the specification (page 17, line 25), structural homology modeling identified these sequences as unique to CYP peptides in the same region predicted to be located on a particular external aspect of the CYP1B1 protein. VNQWSVNHDPVKWPN represents amino acids 422 to 436 of the protein and PENFDPARFLDKDGL represents amino acids 437 to 451 of the protein (see Table 1). Each sequence was found effective at detecting CYP1B1 with high specificity by immunoblotting. Because the sequences share a common inventive linkage, according to PCT rule 13.1, the restriction between the sequences should be withdrawn.

According to the rule of *In re Harnisch*, the restriction is improper. The Action has suggested the peptides lack a structural relationship, and therefore lack unity of invention according to *In re Harnisch* 631 F.2d 716, 206 USPQ 300 (1980). However, the Court made it quite plain that showing a lack of unity of invention is a high hurdle. In the case of *Harnisch*, the Office failed to show a lack of unity because the subject Markush members at issue were all dyes and could, accordingly, be classified together in a manner that was not "repugnant to scientific classification." *Id.* at 305. Applicants note that it can not reasonably be considered repugnant to

scientific classification to group together two related sequences, continuations of each other on an identified antibody accessible region of the same protein, and both functioning to induce antibodies uniquely identifying the protein. Again, Applicants respectfully request at least restriction within claims between the identified sequences be withdrawn.

It would not be a serious burden on the Office to search and prosecute the present application based on the proposed grouping. In fact, prosecution of the 25 claims in 8 groups would severely increase the administrative workload on the Office, reduce prosecution efficiency and greatly delay prosecution in this case.

The present restriction restricts claims according to two alternate peptide sequences. However, searching claimed subject matter for the alternative sequences would not present a substantial burden for a variety of reasons. For example, the international classification of the claimed matter is the same no matter which sequence is involved. The sequences are substantially unique, limited in number and well defined, so it is a simple matter to determine if art describing other limitations of the claim also include the sequences. The sequences are subject to easy, quick, and definite searching by simply cutting and pasting the sequences into available search engines. For example, the additional search of VNQWSVNHDPVKWPN would be most efficiently completed at the time the Examiner has already made the effort to establish search parameters for to the first sequence - by Boolean searching in the alternative for the first search, or by simply pasting VNQWSVNHDPVKWPN to quickly follow up on the first search.

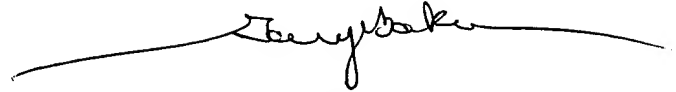
Recent proposals from the Office make it clear that a front loaded approach to prosecution is valued. Applicants respectfully request a condensed and efficient consideration of claim groups in this case.

Of course, non-elected claims and species, withdrawn from current examination, are not cancelled. Applicant respectfully request that all species, elected and non-elected, be eventually considered in this case, as required under MPEP section 803.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 510-337-7871, prior to issuing a Final Office Action.

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gary Baker", written over a horizontal line.

Gary Baker
Reg. No: 41,595

Attachments:

- 1) A petition to extend the period of response for 2 months;
- 2) A transmittal sheet;
- 3) A fee transmittal sheet; and,
- 4) A receipt indication postcard.